TITLE **REGULATION FOR SCHEME OWNERS APPLYING FOR ACCEPTANCE FOR ACCREDITATION BY ACCREDIA OF NEW CONFORMITY ASSESSMENT SCHEMES AND THEIR REVISION**

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NOTE *The present document represents the English version of the document under reference at the specified revision. In case of conflict, the Italian version will prevail. To identify the revised parts reference must be made to the Italian version only.*

PREPARATION

THE DIRECTOR OF CERTIFICATION AND INSPECTION DEPARTMENT

APPROVAL

THE DIRECTIVE COUNCIL

AUTHORIZATION

THE PRESIDENT

APPLICATION DATE

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0.1. SCOPE OF APPLICATION

The purpose of the present Regulation is to regulate the relationship between Scheme Owners (SOs) requesting acceptance by ACCREDIA to obtain accreditation of new conformity assessment schemes (mainly for products/services/process and persons and also in certain cases for management and inspection, verification and validation systems). It is not applicable in cases where the CAS is:

- based on a normative document (e.g. ISO Standards, ISO/PAS Publicly Available Specifications, ISO/TS Technical Specifications, ISO/TR Technical Reports) or other documents issued by standardization bodies (e.g. IWA of ISO, PAS of BSI, CWA of CEN, PdR of UNI);
- applicable internationally and is based on an official standard (UNI, ISO, BSI ..);
- a regulated scheme in accordance with a national or European law;
- has already been positively evaluated by all EA members according to the document EA 1/22, or by IAF/ILAC.

In cases where a SO, in the capacity of a CAB, decides to apply for the accreditation of a conformity assessment scheme for which it has requested acceptance, the requirements of the General Regulation for Accreditation, RG-01 General Part and the requirements of the Regulations for Accreditation specific for the accreditation standard, are also applicable.

The present Regulation is applicable to SOs seeking acceptance by ACCREDIA of a conformity assessment scheme.

0.2. NORMATIVE REFERENCES

The normative references for the application of the present Regulation are as follows:

- Reg. (CE) 765/2008 which sets out the requirements for accreditation relating to the marketing of products;
- UNI CEI EN ISO/IEC 17000 "Conformity assessment, vocabulary and general principles";
- UNI CEI EN ISO/IEC 17011 "General requirements for accreditation bodies accrediting conformity assessment bodies";
- UNI CEI EN ISO/IEC 17020 "Conformity assessment – Requirements for the operation of various types of bodies performing inspections";
- UNI CEI EN ISO/IEC 17021-1 "Requirements for bodies providing certification of management systems";
- UNI CEI EN ISO/IEC 17024 "Conformity assessment – general requirements for bodies providing certification of persons";
- UNI CEI EN ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories";
- UNI CEI EN ISO/IEC 17029 "Conformity assessment — General principles and requirements for validation and verification bodies";
- UNI CEI EN ISO/IEC 17065 "Conformity assessment – general requirements for bodies certifying products, processes and services";

- UNI CEI ISO/IEC 17007 "Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment ";
- UNI CEI ISO/IEC 17067 "Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes";
- UNI EN ISO 14065 "Greenhouse gases – Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition";
- ISO/IEC PRF TR 17028 "Conformity assessment – Guidelines and examples of a certification scheme for services";
- UNI CEI ISO/IEC TR 17026 "Conformity assessment – Example of a certification scheme for tangible products";
- EA-1/22 A:2020 "EA procedure and criteria for the evaluation of Conformity Assessment Schemes by EA Accreditation Body Members";
- EA 1/06 A AB:2020 rev.08 "EA Multilateral Agreement Criteria for signing. Policy and procedures for development" republished October 2015.

The present Regulation also refers, when and to the extent that they are applicable, to the ACCREDIA documents in the current version in force:

- ACCREDIA pricelist (TA-00);
- Agreement between ACCREDIA and the Scheme Owner (CO-04);
- Application for the acceptance of a conformity assessment scheme different from the certification of persons ISO/IEC 17024 (DR-02);
- Application for the acceptance of a conformity assessment scheme for the certification of persons ISO/IEC 17024 (DR-04);
- Circulars (where applicable).

All the above documents are applicable in their current version.

0.3. ACRONYMS

AB: Accreditation body;
CdA: Committee for Accreditation Activities;
CD: ACCREDIA Directive Council;
CAB: Conformity Assessment Body;
SO: Scheme Owner (owner of the conformity assessment scheme);
CAS: Conformity Assessment Scheme.

0.4. TERMS AND DEFINITIONS

Conformity assessment: demonstration that the specific requirements have been complied with.

Conformity Assessment Scheme (CAS): a conformity assessment scheme, as defined in the standard UNI CEI EN ISO/IEC 17000, is a documented and publicly available set of requirements establishing as follows:

- the object of the conformity assessment (e.g. product, process, service, system, person) for assessment;
- the requirements against which the conformity assessment is to be performed;
- the modalities followed to determine conformity, e.g. tests, inspections, verification, validation or audits as well as for all other activities carried out to ensure conformity;
- every requirement made by the Scheme Owner (SO) with regard to the CAB and every specific request and/or interpretation, where applicable.
- every requirement or interpretation of UNI CEI EN ISO/IEC 17011, where applicable.

NOTES:
- a conformity assessment scheme is defined as ***"regulated/mandatory"*** when it is required by laws or by national or international regulations.
- a conformity assessment scheme is defined as ***"voluntary"*** when there are no requirements of the law or of national, European or international regulations. A voluntary conformity assessment scheme shall, nevertheless, take into consideration any mandatory factors related to the object of the certification.

Scheme Owner – (SO) § 2.2 of EA-1/22 defines a SO as an identifiable organization which has established a CAS and which is responsible for the development of the CAS. The following are examples of SOs:
- Standardization bodies(1);
- CABs;
- Organizations that use services provided by CABs;
- Organizations that sell or buy products subject to conformity assessment activities;
- Manufacturers or associations of manufacturers that have established their own CAS;

National accreditation bodies (NABs) cannot be scheme owners.
NOTE: ACCREDIA, as the sole national accreditation body (NAB), cannot be a SO.

Private provision: a document developed by one or more interested parties without the involvement of the Standardization Body;

Standard: according to Reg. EU 1025 of the European Parliament and of the Council of Oct. 25, 2012, concerning the European standardization, the term "standard" is used to mean: *"a technical specification adopted by a recognized standardization body for repeated or continuous application, with which compliance is not compulsory, and which belongs to one of the following categories":*

- **international standard**: a standard adopted by an international standardization body;
- **European standard**: a standard adopted by a European standardization organization;
- **harmonized standard**: a European standard adopted on the basis of a request made by the Commission for the application of Union harmonized legislation;
- **national standard**: a standard adopted by a national standardization body.

Note: (1) Does not include cases where the scheme is fully defined in the standard and the role of the standardisation body is limited to the issue of the standard.

Standards, therefore, are documents which define the characteristics (size, performance, environment, quality, safety, organizational etc.) of a product, process or service, in accordance with the state of the art, and standards are the result of the work many experts in Italy and worldwide. The special characteristics of technical standards are as follows:

- consensus: a standard must be approved with the consent of those who took part in the work;
- democratic participation: all the interested parties may participate in the work and, above all, everyone may offer observations during the process which precedes final approval;
- transparency: UNI indicates the fundamental steps in the process of approval of the drawing up of the standard and keeps the project available for those interested;
- voluntary aspect: standards are a reference which the interested parties accept voluntarily.

1. REQUIREMENTS AND INFORMATION FOR REQUESTING ACCEPTANCE FOR THE ACCREDITATION OF A CONFORMITY ASSESSMENT SCHEME

A SO in conformity with §2 below may make a written, verbal or email request to ACCREDIA to know the details concerning acceptance for accreditation of a conformity assessment scheme.

Upon receipt of the request, ACCREDIA informs the SO of its website address from which it can download the format for the application for acceptance (DR-02 or DR-04) to be sent completed and with all the required attachments.

Upon receipt of the applications DR-02 and DR-04, ACCREDIA goes ahead with the assessment in accordance with the requirements as set out in §4.2 of the Procedure PG-13-01.

This procedure includes a preliminary review of the SO's application on the part of ACCREDIA's Directive Council and the Committee for Accreditation Activities which have the right to express a negative opinion with regard to going ahead with the technical review of the scheme presented. Such decision, giving reasons, shall be communicated to the SO.

If the SO intends to use its own CAS on a European level and seeks acceptance of the scheme for the purpose of European accreditation, it shall send the English version of DR-02 or DR-04 and it shall comply with the requirements of the document EA-1/22.

ACCREDIA shall follow the provisions of §4.2 of EA-1/22 and prepare all the documentation and fill in the format provided by EA for sending all the documentation of the CAS, requesting, where necessary, additional information from the SO (e.g. evidence of the letters of adhesion to the scheme by foreign authorities). This activity may involve costs for the CAB.

2. GENERAL REQUIREMENTS FOR THE SCHEME OWNER

2.1 The SO shall be a legally recognized entity or part of one, and shall be legally responsible for its activities.

There are three possible situations:

1. the SO is also the CAB offering the conformity assessment service;

2. the SO is not the CAB offering the conformity assessment service. The SO limits itself to setting out the rules;
3. the SO is also the CAB which manages the scheme and sells it in competition with other parties.

2.2 The SO shall have the authority to establish and change the requirements of the CAS.
The SO shall provide evidence that persons with proven suitable competences developed the CAS. The competence in question shall cover both the technical area and the procedures of conformity used.

2.3 The SO shall cooperate with ACCREDIA and shall provide ACCREDIA with feedback with regard to the functioning of the CAS.

2.4 The SO shall be able to demonstrate the need or the support of the market for the CAS. This support may include government initiatives or regulatory necessities. In particular, the number and nature of these interested parties may be different for the various CASs, and demonstration of the market necessity is greater in areas/sectors of a higher risk level (e.g. health, safety, food etc.).

2.5 The conformity assessment process described or chosen by the SO shall come within the scope of one of the three standards UNI CEI EN ISO/IEC 17020, 17065, 17021-1, 17029 and ISO 14065 (the Level 3 standards of the EA MLA agreements; see the document EA 1/06).

2.6 Specific requirements of the CAS placed on CABs by the SO shall not contradict, or exclude, any of the requirements included in the standard as referred to in §2.5 above.

2.7 If a CAS places additional requirements on ACCREDIA (NAB), these shall not contradict nor exclude any requirements of the standard ISO IEC 17011 or of Regulation EU 765/2008 and, where applicable, of the mandatory EA, IAF and ILAC documents.
Any requirements for ACCREDIA and other NABs shall be included in the CAS and shall not be imposed through a memorandum of understanding or other contractual agreements with an individual NAB.

2.8 CASs proposed with reference to the present Regulation shall not contradict nor shall they simply require fulfillment of the mandatory legal requirements for the object of the conformity assessment.

2.9 The SO shall commit to accept the results issued by a CAB accredited by ACCREDIA, provided that the CAB has fulfilled the requirements laid down by the SO.

2.10 The SO shall accept the results issued by a CAB accredited by any Accreditation Body signatory of the EA MLA agreements (for the scheme in question), provided that the CAB itself has applied the requirements set out in the CAS.

2.11 The SO shall demonstrate that the CAS has been validated. Such validation shall be documented and shall include:

- a description of the aims of the CAS;
- a description of the requirements of the CAS;
- an analysis of the adequacy of the established requirements for fulfilling the purpose of the CAS;

- a description of the methods to be used for determining the fulfillment of the requirements;
- in cases of an ISO/IEC 17065 scheme, the identification of the applicable requirements of the relevant international standards. The same applies for a scheme in accordance with ISO/IEC 17020 where tests are referred to.
- an analysis of the adequacy of the described methods to be used for determining the fulfillment of the requirements;
- a decision concerning the conformity assessment activities to be performed (including identification of the applicable conformity assessment standards);
- an analysis of the appropriateness of the selected conformity assessment activities.

2.12 The SO shall have set the condition for reserved use of the CAS by accredited CABs with which a specific agreement has been entered into. This agreement shall guarantee at least that the CABs will use the CAS as it is, without any limitations and without any additions. The SO shall plan for a transition policy of the assessments performed before accreditation of the scheme. The SO shall prepare rules for the approval and operative start of new CABs regarding the scheme.

2.13 The SO shall be responsible for keeping ACCREDIA and the active CABs informed of any relevant information and developments relating to the CAS, including the details of any proposed change in requirement (see §4 below).

2.14 The SO shall provide for payment to ACCREDIA of the costs arising from the review of the CAS.

2.15 The application for review of the CAS shall be accompanied by the SO with the information required in **Annex 1** of this Regulation. The Annex shall be fully and precisely completed by the SO.

2.16 In the preparation of the CAS the SO shall follow the requirements set out in **Annex 2** of this Regulation.

2.17 The SO shall commit to accept the results of the assessment activities performed by ACCREDIA with respect to CABs accredited for a specific CAS, provided that ACCREDIA has operated in conformity with the standard ISO/IEC 17011 and with the relevant applicable normative requirements. ACCREDIA remains responsible for the accreditation process of the CAB (including all modifications to the certificate of accreditation, such as withdrawal or extension, for example).

2.18 In order to guarantee to the market that the scheme belongs fully to the body proposing it and not, therefore, to any other SO, or even to ACCREDIA, it is recommended that the SO legally protects the copyright of its scheme (e.g. registration of it at SIAE).

3. GENERAL REVIEW OF THE CAS

3.1 ACCREDIA performs the review of the CAS using information provided by the SO in Annex 1 of the present Regulation.
Records of the review are kept, including the reasons for acceptance of the CAS or the failures leading to non-acceptance.

3.2 Before beginning the review of the CAS the SO sends information to ACCREDIA, in writing, regarding the following matters:

- does the SO intend to operate the CAS only in Italy or also in other EA member countries? In the first case the SO is informed that the CAS will be reviewed only at national level, and that, should the situation change, ACCREDIA's position with respect to the CAS could be reviewed and modified in line with the full application of EA-1/22;
- the CAS shall not contain requirements which contradict the standard ISO/IEC 17011, or Regulation EU 765/2008, or the accreditation standards and also, where applicable, the mandatory EA, IAF and ILAC documents.

3.3 With regard to the rules of the CAS the SO shall set out the modalities which the CAB follows to carry out the verification of the characteristics as defined in the paragraph above. For example, the audit times which shall be adopted by the CAB for the delivery of its service, including the frequency of surveillance activities (these are elements which determine the cost of the certification and for defining the reliability of the results of evaluation activities), the evaluation modalities (exam testing), the competences of persons involved in the evaluation process (auditors, examiners, decision-makers, persons responsible for the review of the contract…), any market surveillance activities (e.g. mystery audits or market sampling activities).

3.4 The SO shall provide evidence that the parties interested in the CAS have been analyzed and identified.
In particular, the number and nature of such interested parties may be different for the various CASs, and that demonstration of the market necessity is greater in areas/sectors of a higher risk level (e.g. health, safety, food etc.).
It is not compulsory for the scheme to be based only on one standard.
In cases where a scheme is based on a document which was created at an institutional level by all the interested parties the requirement is assumed to be fulfilled (e.g. para- or pre-normative standards or documents issued by standardization bodies or mandatory EA or IAF documents).

3.5 A SO may delegate, partially or entirely, the control of the scheme to an accreditation body, or it may collaborate directly with the accreditation body.
It is therefore, for example, possible for a SO to:

- perform directly audits on parties which evaluate (and sell) the scheme;
- perform an audit on ACCREDIA to see how it maintains control of accredited bodies;
- carry out audits directly on bodies/entities evaluated by the CABs, so as to control the CAB's operations or the management of complaints (if any);
- impose obligatory courses for the CAB's auditors or for ACCREDIA's assessors;
- qualify training courses which may be delivered by various bodies/entities which are not CABs;
- take part, also without its evaluators, also with its own evaluators, in conformity assessment activities performed by the CAB.

If a SO undertakes autonomous activities of the control of the correct implementation of the scheme, it shall commit to share the results in timely manner with ACCREDIA in order for it to be possible that any effects of the results of such control activities of issued accreditations are effectively overseen.

Such requirements are legitimate if they do not infringe the higher level standards (the accreditation standard, the standard ISO/IEC 17011 and Reg. 765/2008).

4. REVISION OF THE CAS

The SO shall inform ACCREDIA regarding any modification made to the CAS.

Any proposals for revision of the scheme shall be communicated in advance to ACCREDA and to the CABs involved so that assessment activities for the transition of accreditations and certifications issued against the new revision are properly performed. In such cases the SO shall define, sharing them with the interested bodies (NAB and CAB) the modalities and timeframe of management of the transition process to the new revision of the scheme; this may require a further evaluation.

In all cases ACCREDIA performs a preliminary assessment of the modifications made to the scheme and decides if it is possible to maintain the validity of the CAS, or if it is necessary to perform a detailed review, the cost of which is met by the SO, before confirming the validity of the scheme.

For the management of small modifications, it is not necessary to repeat the process of the formulation of an opinion by the CdA or approval of the Directive Council.

The cost of analysis of the modifications to a scheme is met by the SO, in line with the current ACCREDIA pricelist TA-00.

If the SO does not inform ACCREDIA of the modification to the CAS, the CAS may be considered inappropriate and the relative accreditations may be suspended.

5. OBLIGATIONS OF THE SCHEME OWNER

Article 4 of the contractual agreement (CO-04) is applicable.

6. OBLIGATIONS OF ACCREDIA

Article 3 of the contractual agreement (CO-04) is applicable with the specification that the ACCREDIA Mark used by accredited CABs may indicate if the scheme (provisions and/or requirements) is based on a standard (all normative documents, including para-normative ones) or on a public normative provision (e.g. a law, a Regulation or an EU directive), i.e. on an owner agreement.

ANNEX 1: INFORMATION TO BE PROVIDED BY SCHEME OWNERS (SO) TO ACCREDIA

The information as required below is mandatory so that a NAB can perform an appropriate evaluation of the CAS. The information received from the SO following the questions and the conclusions of the NAB shall be recorded and kept in the NAB management system. These records shall include the rationale behind the NAB's decision in relation to the CAS and may be requested by other EA NABs. They shall also be available during peer evaluations.

Some of the following points may not be applicable to certain schemes.

1. Is the SO willing to use ACCREDIA as the only contact point for the evaluation of the CAS?
2. Is the CAS currently being used by some CABs under accreditation from any other EA member? If affirmative, specification of the member is necessary. If negative, has it been reviewed by another NAB? Provide details of this evaluation.
3. Provide a complete description of the SO which includes:
   - Name and acronym
   - Type of legal entity
   - Address of head office and web address
   - Organizational structure and statutory documents
   - Brief history
   - Any other activities performed (if considered important)
   - Relations to or links with other organizations and with the authorities, both on a national and international level, if any.
   - Technical areas of activity, for example aerospace, electrical testing, food safety etc.
4. Provide evidence of market need for the scheme.
5. In accordance with which conformity assessment standards does the scheme operate? (For example product certification, testing, etc.) Specify the reasons for the choice and identify the scheme documents where it is defined.
6. Is the CAS intended for national use only? If not, please specify the geographical area of acceptance: a few European countries, all European countries, globally.
7. Has the SO established CAS specific requirements for the operation of CABs intending to operate within the CAS? If affirmative, describe the specific requirements of the CAS and identify the CAS documents where these requirements are described. Specify also how such requirements are made publicly available.
8. Does the SO (autonomously or through another organization) perform any kind of assessment of the CAB? If so, describe it and refer to the CAS document where this condition is described. Does the SO carry out other activities to confirm the recognition of CABs that intend to work within the scope of the CAS, in addition to requiring that they be accredited according to the provisions of the CAS requirements? If affirmative, describe the activity and identify the CAS document(s) where this is stated.
9. If the answer to question 8 is affirmative, does the SO request the NABs to accept or take into account this assessment during the accreditation process? If affirmative, identify the scheme documents where this condition is stated and described.

10. Does the SO request EA or EA Members to cooperate with the SO on other than those related to accreditation? If affirmative, specify the areas of cooperation required and report in which documents of the scheme these aspects are described.
11. Has the SO established CAS specific scheme requirements for ACCREDIA's operations? If affirmative, specify the scheme documents and where these are described.
12. What is the object of the conformity assessment? State as specifically as possible. (The object of the conformity assessment activities may be products, services, materials, installations, processes, systems, persons or bodies).
13. What are the specific requirements regarding the characteristics of the object of assessment? Identify the CAS documents where these are stated.

    Notes:
    - in cases where the CAS that is the object of the application is not based on a document (e.g. ISO Standards, ISO/PAS Publicly Available Specifications, ISO/TS Technical Specifications, ISO/TR Technical Reports) or other documents issued by standardization bodies (e.g. IWA of ISO, PdR of UNI, PAS of BSI, CWA of CEN, etc.), before confirming to the SO the possibility of starting the examination of the scheme, the ACCREDIA Management will ask the SO to explain the reasons for the failure recourse to the Standardization Body;
    - the requirements shall be written in a clear, direct and precise manner and they shall result in accurate and uniform interpretation, so that parties making use of the CAS normative documents are able to derive from their contents an unequivocal interpretation of the relative significances and aims;
    - the requirements shall be written in terms of results, outcomes, together with the values requested and the tolerances permitted (where necessary);
    - the requirements shall be stated unambiguously using wording that is objective, valid and specific.
14. Are all the measurement values requested expressed in SI (International System of Units)?
15. Does the CAS cover the following typical elements of a conformity assessment scheme?
    - **Selection** of the object/s of conformity assessment, including selecting specified requirements to be assessed and planning information collection sampling activities.
    - **Determination**, including the use of one or more methods for the determination (e.g. tests, audits, exams) to develop complete information concerning the fulfillment of the requirements specified by the object/s of the conformity assessment or of a sample of it.
    - **Review and attestation** of evidence gathered during the stage of determination and the resulting attestation that the object of conformity assessment was reliably demonstrated to fulfill the specific requirements, and any resulting marking or licensing and their possible related controls, when applicable.
    - **Surveillance** (where applicable), including the frequency and extent of surveillance activities and reassessments to ensure that the object/s of the conformity assessment continue/s to fulfill the specified requirements.
16. If the CAS requires sampling, what are the necessary procedures? (to obtain consistent and reproducible results the sampling methods should be based, when possible, on statistical methods provided by international standards).

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17. Are there testing methods or procedures of inspection involved in the CAS? Where are they defined?
18. Does the CAS consider the use of marks of conformity? If the answer is affirmative, the SO shall demonstrate that it has protected those marks and defined the rules for their use in accordance with the requirements of the chosen conformity assessment standard.
19. Provide evidence that the CAS was designed by persons who are demonstrably competent in that capacity. The competence shall cover both the technical area of expertise and the conformity assessment procedures used.

    Note: CABs may be involved in the development process of CASs within the limitations given in the standard used for their accreditation.
20. Provide evidence that the parties interested in the CAS have been analyzed, identified, consulted and that every problem has been solved.
21. Provide evidence that the CAS has been validated, taking into account the details contained in §3.1.6 of EA-1/22. As a minimum, the validation shall demonstrate that the CAS has successfully completed a test period, showing that it is fit for the defined purpose. Some of the questions to considered are:
    - is the conformity assessment, as described, practicable?
    - do the determination activities, as described, quantify or in other ways identify and confirm the characteristics which the SO has set identify and which constitute the basis for conformity assessment?
    - are the requirements defined in a way that ensures reproducibility and reliability of results?
22. For the evaluation of existing CASs, the SO shall identify all EA NABs implementing a CAS and demonstrate to the hAB what steps have been taken so that NABs currently accrediting CABs for CAS perform accreditation in a harmonized manner.

ANNEX 2: GUIDANCE REGARDING CONFORMITY ASSESSMENT SCHEMES

This Annex states the guidance criteria to be considered by a SO when designing a CAS in order to facilitate acceptance by ACCREDIA. The criteria defined in this Annex and in other parts of this document reflect the contents of the main ISO/CASCO standards and guides. A complete list of these standards is available from CASCO Toolbox, available on the ISO website (www.so.org).

SOs should follow the standard ISO/IEC 17007 as a general guidance when designing normative documents for conformity assessment, with a particular focus on the principles in §4 and the guidance as set out in §5 and §6.

The standard UNI ISO/IEC 17067 provides the guidelines for understanding, developing, implementing and maintaining certification schemes of products, processes and services. The guidelines are related to:

- SO (§6.3)
- Development of a scheme (§6.4)
- Contents of a scheme (§6.5)
- Maintenance and improvement of a scheme (§6.6)
- Documentation of a (§6.7)

The guidelines below provide examples of certification schemes:

- ISO/IEC 17026 Example of a certification scheme for tangible products;
- ISO/IEC TR 17028 Guidelines and examples of a certification scheme for services;
- ISO/IEC TR 17032 Conformity assessment - Guidelines and examples of a certification scheme for processes.

These guidelines should be applied by SOs establishing certification schemes for products, processes and services. They can also be used in establishing inspection and management system certification schemes as well as for schemes requiring testing and calibration activities.

The requirements for defining certification schemes for persons are contained in §8 of the standard UNI CEI EN ISO/IEC 17024.

The following table gives an overview of the minimum elements that a CAS should consider for different types of activities.

Laboratory activities/procedures for conformity assessment	***Description (minimum)***
Calibration and testing (including exams in the medical area)	• Area of activity (object, matrix, scope, etc.); • Calibration and testing methods; • Performance characteristics of the methods; • Requirements applicable to laboratories, additional to international standards for laboratories (e.g. ISO/IEC 17025 or ISO 15189); • Requirements against which the object shall be tested. These requirements can be contained in international standards, or legal requirements, or sector standards, or specifications issued by groups of manufacturers; • Specific requirements referred to e.g. internal and/or external quality control procedures and/or performance characteristics, if any.
Inspection	• Area of activity (object, matrix, scope, etc.); • Requirements against which the object of the inspection shall be judged. These requirements may be contained in international standards, or legislative references, or sector standards, or specifications issued by groups of manufacturers; • Inspection methods, if necessary, including any examinations that shall be conducted as part of the conformity assessment process; • Requirements applicable to additional inspection bodies with respect to ISO/IEC 17020.
Certification	• The object of the certification: management system or product, service or process or persons (experience and competence). • Requirements against which the object of the certification shall be evaluated and certified. These requirements may be contained in international standards or legal references, sector standards, or specifications issued by groups of manufacturers; • Description of the certification system; • Requirements applicable to certification bodies, additional to the international standards for CABs.

SPECIFIC GUIDANCE ON THE VALIDATION OF CERTIFICATION SCHEMES

Depending on the type of CAS, some of the questions may not be applicable.

1. Object

a) What is the object of the certification?
b) Which (groups of) products/services/processes/systems/competences, does the scheme cover?
c) What aspects of the products/services/processes/systems/competences, does the scheme relate to?

2. Certificate

a) What is the conformity declaration which appears on the certificates?
b) What are the conditions of validity of the certificate and of the declaration of conformity?
c) How is the chosen system of certification indicated?

3. Certification mark

a) Does the use of the mark respect the requirements of the conformity assessment standard?
b) How is the significance of the certification mark communicated to the market?
c) Is there any significant risk of the certification mark being misinterpreted or misused?

4. Certification requirements

a) Indicate the documents of the scheme where the requirements are defined;
b) How is it demonstrated that it is possible to evaluate the requirements?
c) Are the legal requirements included?
d) Does the scheme only contain the legal requirements?
e) How is the compliance with the legal requirements determined?
f) Are there documents explaining or interpreting the requirements?
g) Have the documents referred to in letter "f" above been published?

5. Certification system

a) Which is the method used in order to determine conformity?
b) How can it be demonstrated that the method used is suitable for supporting the declaration of conformity?
c) Which method do you rely on to monitor that the certificate holder continues to comply with the requirements over time?
d) How is it possible to demonstrate the suitability of the method in order to monitor that the certificate holder continues over time to comply with the requirements?

6. Conditions for certification

a) Which criteria are required for granting, maintaining, expanding, reducing, extending, suspending or withdrawing certification?
b) Is the definition of nonconformity in line with the reference standards of the CAB and with the EA/IAF Guides?
c) What rights and obligations are set for the SO, for CABs and for applicants for certification?
d) What records are kept demonstrating continued compliance with the requirements?
e) How are the criteria established related to the handling of complaints by holders of certification?
f) Is the client clearly defined and does it fulfill the requirements of the accreditation standard?
g) How is it demonstrated that the certification requirements substantiate the characteristics of the object to which the declaration of conformity refers?

h) How is it demonstrated that the certification process meets all the requirements of the certification process of the chosen accreditation standard?

7. Procedures

a) Where are the certification procedures described?
b) Has the suitability of the procedures been demonstrated?

8. Competence

a) Have the competence requirements for each stage of the certification process been defined?
b) How is the confirmation of the suitability of the competence requirements carried out?

9. Publicly available information

a) Where are the scheme documents published?
b) Are they publicly available?
c) Does the SO carry out market surveillance activities, e.g. by means of lists of product certificates, certified persons etc.?